

engaged in scientific misconduct in this clinical research supported by NCI, National Institutes of Health (NIH), cooperative agreements.

Specifically, Ms. Diaz intentionally fabricated and/or falsified research data and information collected at RPMC for the Breast Cancer Prevention Trial (BCPT) under the National Surgical Adjuvant Breast and Bowel Project (NSABP) and a secondary prevention trial for lung cancer sponsored by the M.D. Anderson Cancer Center and Eastern Cooperative Oncology Group (ECOG). Ms. Diaz falsified data related to entry criteria and treatment compliance on the secondary lung cancer prevention trial. She fabricated reports of follow-up examinations for subjects entered on the BCPT, falsified laboratory test results, and forged signatures of physicians on informed consent documents.

ORI has implemented the following administrative actions for the three (3) year period beginning March 13, 1999:

(1) Ms. Diaz is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) Any institution that submits an application for PHS support for a research project on which Ms. Diaz's participation is proposed or which uses her in any capacity on PHS supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of her duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of Ms. Diaz's research contribution. The institution also must submit a copy of the supervisory plan to ORI.

FOR FURTHER INFORMATION CONTACT: Acting Director, Division of Research Investigations Office of Research Integrity 5515 Security Lane, Suite 700 Rockville, MD 20852 (301) 443-5330.

Chris B. Pascal,

Acting Director, Office of Research Integrity.
[FR Doc. 99-7234 Filed 3-24-99 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P-0043]

Agency Information Collection Activities; Announcement of OMB Approval; Food Labeling: Nutrition Labeling of Dietary Supplements on a "Per Day" Basis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Food Labeling: Nutrition Labeling of Dietary Supplements on a "Per Day" Basis" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 12, 1999 (64 FR 1765), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-395. The approval expires on March 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at "http://www.fda.gov/ohrms/dockets".

Dated: March 17, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99-7233 Filed 3-24-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F-0487]

Exxon Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Exxon Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of fatty acids, C10-13-branched, vinyl esters as a comonomer in polymers used as components of adhesive formulations intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4650) has been filed by Exxon Chemical Co., P.O. Box 3272, Houston, TX 77253-3272. The petition proposes to amend the food additive regulations in § 175.105 Adhesives (21 CFR 175.105) to provide for the safe use of fatty acids, C 10-13-branched, vinyl esters as a comonomer in polymers used as components of adhesive formulations intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 5, 1999.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99-7231 Filed 3-24-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 77N-0240; DESI 1786]

Nitroglycerin Transdermal System; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is proposing to withdraw approval of one new drug application (NDA) and five abbreviated new drug applications (ANDA's) for certain single-entity coronary vasodilator drug products containing nitroglycerin in a transdermal system.